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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,383	08/21/2003	Vincent G. Copa	AMS0008/US	9726

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EXAMINER

YABUT, DIANE D

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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05/24/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/646,383	Applicant(s) COPA ET AL.	
	Examiner DIANE YABUT	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-14 and 26-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-14 and 26-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 03/01/2010.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 9, 11-12, 14, 26-29, 35, 39, and 43 are rejected under 35

U.S.C. 102(b) as being anticipated by **Sharkey et al.** (U.S. Patent No. **5,540,701**).

Sharkey et al. disclose an anastomosis device comprising a hollow, elongate flexible catheter body **18** having a proximal end and a distal end, the distal end comprising a catheter body wall, an inflatable balloon **32** at the distal end, a drainage aperture **28** at the distal end and a drainage means **22** connected to the drainage aperture for draining urine from a bladder extending to a port at the proximal end, and a tissue approximating structure or inflatable balloon **36** that can be extended (inflated) and retracted (deflated), from the catheter body wall along the distal end of the catheter body on a proximal side of the inflatable balloon for holding severed tissue in contact for healing, wherein the inflatable balloon is on a proximal side of the drainage aperture (Figures 9, 11, 13). The device may be installed in a body having a prostate removed, with the catheter inside of the urethra and the balloon in the bladder, the tissue

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approximating structure being capable of contacting tissue selected from tissue of a bladder, tissue of a perineal wall, urethral tissue, and combinations of these (col. 6, lines 51-65). An actuating (inflation) means is connected to the tissue approximating means and extends from the tissue approximating means to the proximal end.

In regards to claims 26-29, the first tissue approximating structure may be considered to be the first inflatable balloon **32** and the second tissue approximating structure may be considered to be the second inflatable balloon **36**, both which are located on a proximal side of the drainage aperture **28**, wherein each of the first and second tissue approximating structures can be extended and retracted (inflated and deflated) from the catheter body wall.

The balloon or the first tissue approximating structure **32** and the second tissue approximating structure **36** may both be extended and retracted at a fixed location along the distal end of the catheter body with respect to the distal and proximal ends of the catheter body.

The tissue approximating structures or balloons may be elongate structures since the geometry of the balloons may "impart various geometrical configurations that are then used to expand proximal and distal ends **12** and **14**" which may be conical (col. 7, lines 23-41), or "a generally cylindrical shape" (col. 5, lines 50-59).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 3-8, 13, 30-34, 36-38, 40-42, 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Sharkey et al.** (U.S. Patent No. **5,540,701**) in view of **Kirsch et al.** (U.S. Patent No. **6,461,367**).

Sharkey et al. disclose the claimed device except for the tissue approximating structure or the second tissue approximating structure comprising of multiple distal tines and multiple proximal tines that all extend and retract from the catheter body wall at fixed locations along the distal end of the catheter body, the fixed locations being fixed with respect to the distal and proximal ends of the catheter body.

In Figures 1-9 Kirsch et al. teach multiple distal tissue approximating tines **30** *on **24**) and opposing multiple proximal tissue approximating tines (on **16**; see col. 3, lines 48-55) that all extend and retract from a catheter body wall at fixed locations along the distal end of the catheter body, the fixed locations being fixed with respect to the distal and proximal ends of the catheter body. For instance, when the distal end **24** of the catheter body and the proximal end **16** of the catheter body are fixed or connected together, the distal tines may be extended and retracted by actuating knob **28** at a fixed location through apertures **46**, and similarly the proximal tines may be extended and retracted by actuating knob **18** through apertures at a fixed location (Figures 1 and 5;

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see col. 3, line 32 to col. 4, line 14). Opposing tines **30** may also be used as shown in Figures 11A-B.

It would have been obvious to one of ordinary skill in the art at the time of invention to replace the (second) tissue approximating structure of Sharkey et al. with one that comprises multiple distal and proximal opposing tines at the distal end of a catheter body, as taught by Kirsch et al. in order to facilitate the approximation of tissue portions by anchoring the urethral stump and bladder neck with tines to ensure proper connection between the urethra and bladder (col. 1, lines 38-40, Kirsch et al.), as well as to selectively approximate tissue when desired.

Sharkey et al. also acknowledge that instead of the inflatable balloon tissue approximating structures **32** and **36** that “distensible members that are mechanically extended and retracted in order to deploy the proximal and distal ends **12** and **14** of [the anastomosis device]” may be used (col. 7, lines 15-22), and therefore it would have been obvious to one of ordinary skill in the art to consider the teaching of distal and proximal selectively retractable tines of Kirsch et al. for deploying the anastomosis device in Sharkey et al.

Response to Arguments

5. Applicant's arguments filed 03/01/2010 have been fully considered but they are not persuasive.

6. Applicant argues that the tissue approximating structure or balloons **32**, **36** of Sharkey et al. cannot be considered elongate. The examiner disagrees. As mentioned above, the tissue approximating structures or balloons may be elongate structures since

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the geometry of the balloons may "impart various geometrical configurations that are then used to expand proximal and distal ends **12** and **14**" which may be conical (col. 7, lines 23-41), or "a generally cylindrical shape" (col. 5, lines 50-59) and therefore may be considered elongate structures.

7. Applicant also argues that the everting prongs of Kirsch et al. would not be used to modify the tissue approximating structures/balloons of Sharkey et al. since the minimal and non-expanding surface area of the prongs of Kirsch et al. would not function similarly as the expanding surface area of the balloons in Sharkey et al. However, as mentioned above, Sharkey et al. suggest that the balloons may be substituted with "distensible members that are mechanically extended and retracted in order to deploy the proximal and distal ends **12** and **14** of [the anastomosis device]" (col. 7, lines 15-22), and therefore it would have been obvious to one of ordinary skill in the art to consider the teaching of distal and proximal selectively retractable tines of Kirsch et al. for deploying the anastomosis device in Sharkey et al., and since it was well known in the art to use radially expandable structures as alternatives to radially inflatable structures.

8. Lastly, applicant argues that Kirsch et al. in Figures 1-5 do not teach opposing tines. However, as mentioned above, in other Figures 11A-13 opposing tines **30** may be used, and therefore read on the limitation.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/TODD E. MANAHAN/
Supervisory Patent Examiner, Art Unit 3734